

Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, Food and Drug Administration 200 C SLSW. Washington DC-20204

October 31, 2003

Aboca USA Inc., located at 126 South Spokane Street/Suite C, Seattle - Washington 98134, submits the following notification of marketing in the United States of an herbal supplement imported from Italy. Aboca will sell the product to medical practitioners and qualified retailers in the USA.

### NOTIFIES

The marketing of the following Herbal Supplement:

California Poppy Flowering Top Herbal Supplement **Brand Name:** 

0.95 Oz (27.0 g) 90 Capsules in glass bottle Presentation:

Aboca S.p.a., Via della Liberta' 37/ter - Pistrino di Citerna Name and address of the manufacturer:

Perugia - Italy

Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Name and address of the distributor:

Washington - 98134 USA

California Poppy (Eschscholzia californica) promotes TEXT OF THE STATEMENT:

relaxation and normal sleeping patterns.\*

\*This statement has not been evaluated by the Food and Drug Text of the disclaimer:

Administration. This product is not intended to diagnose, treat, cure

or prevent any disease.

HERBAL INGREDIENTS (Amount per serving: 1 Capsule):

^ California Poppy (flowering top) - W.P.C. \*\* 220 mg

975 0162 LET /3387

OTHER INGREDIENTS:

Gelatin (capsule).

86626

\*\*WPC:

"Whole Phytocomplex Concentrate" (W.P.C.) is a combination of freeze dried extract with the powder of

the same portion of the plant.

^ = Certified organic (EU Directive 2092/91)

**WARNING:** 

Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your

health care practitioner. Keep out of reach of children.

I Anna Tucci, Executive Vice-President and General Manager of Aboca USA, certify that all the information presented and contained in this notice is complete and accurate, and that Aboca USA has substantiation that the statement is truthful and not misleading.

Anna Tucci

Executive Vice-President

Aboca USA



SUGGESTED USE: Take 1 capsule three times a day, one during the day and two before going to bed, or as directed by a qualified health care

# Supplement Facts Serving size: 1 capsule Servings per contained: 90

Calories, 1.0

Amount Per Serving mg % Daity Value

#Catifornia Pappy - W.P.C." 220 "
(Eachscholzie celfornice) (flowering top)
Stendardized to 0.046% protopine, yielding 0.1 mg per capsule

Other ingredients: gelatin (capsule).

% Daily Value not established

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#### Aboca: Growing Herbs for Health

Since 1978, Aboca has grown herbs using organic farming processes. Today Aboca's farmlands occupy over 1700 acres, all certified organic in accordance with EU Directive 2092/91. Our mission is to provide the safest and most effective herbal supplements, by combining the ancient tradition of herbal remedies with the most sophisticated scientific research and production technology. Aboca is committed, from seed development to final packaging, to making the world's most natural herbal products for health needs, without the use of any chemical excipients or additives.

> To learn more about Aboca, visit: www.aboca.us

MADE IN ITALY

The derk glass bottle is temper resistent for your protection, preserving this product from air, moisture and microbial

Outer box prevents any further exposure to the light, fully ensuring its original stability and potency. All materials are completely recyclable. Keep in a dry cool place.

Herbal Supplement

## California Poppy



#### Whole Phytocomplex Concentrate Freeze-Dried Micronized Plant Extract

220 mg per capsule

Catifornia Poppy (Eschscholzia californica) promotes relaxation and normal sleeping patterns."

This plant is cultivated from Aboca's organic farms. Systematic quality controls implemented throughout the entire production process and analytical testing performed on raw material and finished product validate the safety and effectiveness of this herbal production. supplement.

Though protopine is considered one of the main active ingredients of California Poppy, many other plant components contribute to the herb's

other plant components contribute to the herb's efficacy. That is why Aboce has developed the exclusive W.P.C. W.P.C. Whole Phytocompiex Concentrate) is a combination of the freeze-dried extract with micronizad powder from the same portion of the plant, to assure maximum blosvellebility, optimum concentration of active principle and the full-spectrum of constituents.

The result is a product with uniform content of prutopine without the use of exciplents, colorings, flavorings, or preservatives. GMO free.

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treet, cure or prevent any disease.

Har Wild State (17, Eg) (10 Capables

Manufactured by: Asses SuiA. Via dulla Lucerdi 37/fei - Pistriko di Oterna, Perogna - Buly Distributed by: Abusar Usis Inc. 126 South Spokene Street/Suite C. Seattle - Wasfangton - 98134 USA

ASUSESCOLOPW-A

Best before Batch No.:

